

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: July 14, 2005

ACTION MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for Xanthan Gum - Modified

FROM: Dan Rosenblatt, Chief
Minor Use, Inerts, and Emergency Response Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert exemption from the requirement of a tolerance. The tolerance exemption is to be maintained.

Chemical: Xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight). *NOTE: for ease of reading in this document, this chemical will be referred to as "xanthan gum-modified"*

CFR: 40 CFR § 180.910

CAS #: 375348-43-9

Use Summary: Produced from the fermentation of corn sugar, xanthan gum is used as a thickener, emulsifier, and stabilizer in foods such as dairy products and salad dressings. Xanthan gum-modified is used as a surfactant in pesticide products applied to growing crops or to raw agricultural commodities after harvest.

Table 1. Tolerance Exemption Being Reassessed in this Document

Tolerance Exemption Expression	CAS Reg No.	40 CFR §	Use Limitation	Use (Pesticidal)
Xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight).	375348-43-9	180.910 ¹	Not more than 0.5% of pesticide formulation.	Surfactant

1. Residues listed in 40 CFR § 180.910 are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to growing crops or to raw agricultural commodities after harvest.

The current exemption for xanthan gum-modified was established on May 3, 1996 (61 FR 19854). The rationale used in establishing the exemption was given in the proposed rule (February 7, 1996; 61 FR 4621), and is provided below:

1. Xanthan gum-modified, is a glyoxal-treated xanthan gum that, while similar to xanthan gum, has improved dispersion properties.
2. Xanthan gum is a naturally occurring high molecular weight biopolysaccharide which is already exempted from the requirement of a tolerance when used as a thickener in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (40 CFR § 180.910) and when used in pesticide formulations applied to animals (40 CFR §180.930).
3. Glyoxal is cleared for use as a component of coated or uncoated food contact surface paper and paperboard (21 CFR §176.180 (b)(2)). (*NOTE: this has not changed*)
4. Hydrolysis of xanthan gum-modified results in the formation of xanthan gum and sodium glycolate, which is toxicologically similar to oxalic acid.
5. Based on an estimation of dietary exposure utilizing a worst-case situation in which a pesticide formulation utilizes modified xanthan gum containing 0.3% glyoxal, the resultant dietary exposure to glyoxal would be considered to be of no toxicological concern.
6. A pesticide formulation containing modified xanthan gum with a 0.1 to 0.3% glyoxal concentration would typically contain from 2.9 to 7.5 ppm (parts per million) glyoxal. At these levels, it is considered to be of low ecological effects or environmental fate concern.

A review of available information developed since the establishment of the exemption did not reveal any data that would alter the original "minimal or no risk" conclusion. Therefore, the human health and ecological risk findings used to establish the exemption still apply. Because this exemption was established three months prior to FQPA, additional safety findings are now required and are found below.

Special Considerations for Infants and Children: Xanthan gum-modified is of low toxicity for endpoints of concern for human health effects, including developmental and reproductive effects, based on the available information. Therefore, there is no concern for potential sensitivity to infants and children. For glyoxal alone, fetotoxic effects occurred only with doses that induced maternal toxicity. No risks were identified for xanthan gum alone. Based on this available information, a safety factor analysis has not been used to assess the risks resulting from the use of xanthan gum-modified, therefore, an additional tenfold safety factor for the protection of infants and children is unnecessary.

Aggregate Exposures: In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In developing this assessment for xanthan gum-modified, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to this chemical.

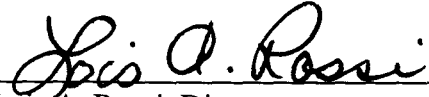
Cumulative Exposure: Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the

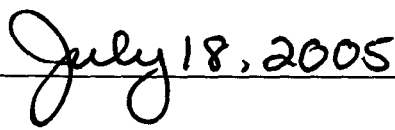
cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to xanthan gum-modified and any other substances, and xanthan gum-modified does not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that xanthan gum-modified has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>

Human Health Risk Characterization: Taking into consideration the available information on xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight), there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight) in/on raw agricultural commodities under 40 CFR §180.910 can be considered reassessed as safe under section 408(q) of the FFDCA.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight) (CAS# 375348-43-9). I consider the one exemption established in 40 CFR § 180.910 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.


Lois A. Rossi, Director
Registration Division

Date: 

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD